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## UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	2727-110
First Inventor or Application Identifier	Wilfried Fischer
Title	Patch With Reduced Cold Flow
Express Mail Label No.	EK839446714US

### APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

1. Fee Transmittal Form (e.g., PTO/SB/17)  
(Submit an original and a duplicate for fee processing)
2. Specification [Total Pages **12**]
  - Descriptive title of the invention
  - Cross References to Related Applications
  - Statement Regarding Fed sponsored R & D
  - Reference to Microfiche Appendix
  - Background of the Invention
  - Brief Summary of the Invention
  - Brief Description of the Drawings (if filed)
  - Detailed Description
  - Claim(s)
  - Abstract of the Disclosure
3. Drawing(s) (35 U.S.C. 113) [Total Sheets ]

4. Oath or Declaration [Total Pages ]

- a. Newly executed (original or copy) **UNSIGNED**
- b. Copy from a prior application (37 C.F.R. § 1.63(d))  
(for continuation/divisional) with Box 17 completed  
(Note Box 5 below)

L  DELETION OF INVENTOR(S)  
Signed statement attached deleting  
inventor(s) named in the prior application,  
see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

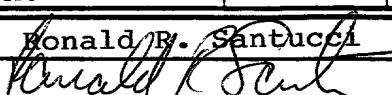
5.  Incorporation By Reference (useable if Box 4b is checked)  
The entire disclosure of the prior application, from which a  
copy of the oath or declaration is supplied under Box 4b, is  
considered to be part of the disclosure of the accompanying  
application and is hereby incorporated by reference therein.

17. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in a preliminary amendment

Continuation  Divisional  Continuation-in-part (CIP) of prior application No:

Prior application information: Examiner  Group / Art Unit:

### 18. CORRESPONDENCE ADDRESS

<input type="checkbox"/> Customer Number or Bar Code Label (Insert Customer No. or Attach bar code label here)	<input type="checkbox"/> Correspondence address below
<p>Name: Ronald R. Santucci Pitney, Hardin, Kipp &amp; Szuch, LLP Address: 711 Third Avenue, 20th Floor City: New York State: New York Zip Code: 10017 Country: U.S.A. Telephone: 212-687-6000 Fax: 212-682-3485</p>	
Name (Print/Type): Ronald R. Santucci	Registration No. (Attorney/Agent): 28,988
Signature: 	Date: 06/23/00

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2727-110

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Wilfried Fischer, Hubert Kaffl, Petra Huber and  
Clifton Zimmermann

U.S. Serial No.: Art Unit:

Filing Date: herewith Examiner:

For: PATCH WITH REDUCED COLD FLOW

**PRELIMINARY AMENDMENT**

Box Patent Application  
Commissioner for Patents  
Washington, D.C. 20231

S I R:

Preliminary to examination of the above-identified  
application kindly amend the application as follows:

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In the Claims:

In claim 3, line 1, kindly delete "one of the preceding claims" and substitute therefor --claim 1--;

In claim 5, line 1, kindly delete "or 4";

In claim 6, line 1, kindly delete "or 5".

REMARKS

Consideration of the application as preliminarily amended is respectfully requested. The claims have been amended to remove multiple dependencies. No new matter has been added.

Respectfully submitted,

  
Ronald R. Santucci  
Registration No. 28,988

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10 US 10836

Novosis Pharma AG15 **Plaster having reduced cold flow**

20 The invention refers to a plaster having reduced cold flow.

25 **1. Introduction and state of the art**

30 In the following, the term "plaster" is intended to mean self-adhering, flat coverings which are to be applied to the human skin. The plasters can be of a single- or multi-layer construction and can consist of films, woven fabrics or non-woven fabrics in combination with self-adhering polymers. In addition, the plasters can contain any desired pharmaceutical or cosmetic active agents or also be free of active agent. They can be applied to healthy or damaged skin.

35 The adhesive of the plasters generally exhibits a flowability which is sufficient so that it can flow around unevennesses or roughnesses of the skin and thereby result in a good bond to the skin. Very "hard" adhesives which have glass transition

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temperatures of more than 10 to 20 °C usually do not adhere well to the skin. On the other hand, however, if the adhesive exhibits good flow behavior, a small amount of adhesive can escape at the cut edges of the final plaster during storage or when it is worn (so-called "cold flow"). The adhesive which has escaped can, e.g., adhere to the packaging material during storage or adhere to the surrounding clothing or other articles which are in contact to the skin during the duration of application to the skin.

After having been worn for some time such plasters exhibit a cosmetically very displeasing "dirty fringe" which is generally formed by fibers of clothing or other particles which adhere to the adhesive composition which escapes at the cut edge. The dirty fringe can occur directly on the skin outside of the plaster or under the external edges of the plaster.

The object of the invention is to eliminate these deficiencies connected to the state of the art.

This object is achieved according to the invention by a plaster having reduced cold flow with the features recited in claim 1.

Further advantageous embodiments are subject matter of the dependent claims.

## 2. Detailed description of the technical solution

The above described disadvantages of the state of the art are avoided by the combination of at least two adhesives which are applied to the plaster in a spatially separated manner.

To this end, the layer of adhesive of the actual plaster ("inner layer of adhesive" or "plaster core"; also abbreviated as "core") which, e.g., contains a pharmaceutically active agent is surrounded with a second layer of adhesive ("outer layer of adhesive" or "ring of adhesive"; also abbreviated as "ring") which mechanically prevents that the adhesive of the inner layer escapes. It is clear that this "ring", as long as it fulfills its function, can have any form and, for example, when viewed from above, can be circular, oval or even square or rectangular, and optionally have rounded edges. The skilled person chooses the suitable form according to the practical conditions.

Generally, the inner layer of adhesive is rendered sufficiently flowable and tacky by pharmaceutical or cosmetic active agents or other additives such as resins or plasticizers, so that the inner layer of adhesive provides a good and permanent bond to the skin.

In contrast thereto, the outer layer of adhesive possesses stronger cohesion and thus lower flowability than the inner layer of adhesive because plasticizing additives are missing or are contained in a lesser amount or because it consists of a different polymer or mixture of polymers which does not flow to such a high extent. Thus, cold flow at the cut edge of the plaster is prevented or reduced to such an extent that adherence to the packaging material or occurrence of a dirty fringe on the skin, if the plaster is worn for a longer time, can be reduced or even prevented. Simultaneously, the flowable inner layer of adhesive is mechanically prevented from escaping.

According to the simplest case in the prior art, plasters are prepared by applying a solution or dispersion of adhesive onto a film, woven fabric or non-woven fabric by spreading, spraying,

printing or the like and this layer of adhesive is covered with a second film, woven fabric or non-woven fabric after drying. Then, forming of the plaster by die-cutting or cutting and subsequently packaging follows.

5 In contrast thereto, the plasters according to the invention having reduced cold flow can be, for example, prepared as follows.

10 **2.1 Direct coating**

15 **2.1.1 Preparation of the plaster cores**

20 A siliconized film or paper (which, according to its function, in the following is also referred to as "release liner") is coated with the material of the plaster core in a suitable coating machine and subsequently covered with a thin cover film. The plaster cores are die-cut by a die-cutting machine, whereby the die-cutter is to be adjusted so that the siliconized film is not die-cut (e.g., by using the kiss-cut method), i.e. the cores remain on the film. Then the film is wound up.

25 **2.1.2 Preparation of the plasters with cores and rings of adhesive**

30 The wound film of 2.1.1 with the plaster cores adhering thereto is further coated with the material of the ring of adhesive in a coating machine so that the voids between the cores are filled with the material of the ring. Coating is conducted in such a manner that the cover film of the plaster cores is only coated to a minimal extent. After drying (if necessary), the layer of

adhesive between the cores should possess the same thickness as the total thickness of the plaster cores. Optionally, coating is repeated as many times as necessary until the thickness has reached the desired value. Then, a second cover film is applied

5 as a cover so that this film uniformly covers both the material of the ring of adhesive as well as the cover film of the plaster core.

10 In a further die-cutting step, the final plasters are then die-cut out of the laminate. In this step, die-cutting tools are used having a diameter which corresponds to the diameter of the plaster cores plus twice the breadth of the ring of adhesive.

15 **2.2 Separate direct coating**

According to this embodiment plaster cores, rings of adhesive and a common, adhesive-coated cover film are prepared separately. The cover film connects the plaster cores and rings 20 of adhesive in subsequent step.

**2.2.1 Preparation of the plaster cores**

25 The preparation corresponds to the preparation in 2.1.1.

**2.2.2 Preparation of the rings of adhesive**

30 A siliconized film or paper is coated with the material of the ring of adhesive in a suitable coating machine and subsequently covered with a thin cover film. Rings of adhesive are die-cut by a die-cutting machine, whereby the die-cutter is to be adjusted

so that the siliconized film is not die-cut, i.e. the rings remain on the film. Then the film is wound up.

5    2.2.3 Preparation of the adhesive-coated cover film

A thin, non-siliconized film or film siliconized on one side (e.g., Hostaphan MN 15) is coated with a layer of pressure-sensitive adhesive, for example, a hot melt PSA or a UV cross-linked PSA, at a coating weight of approximately 1 to 20 g/m<sup>2</sup>. This coating step can be conducted in a separate coater or directly in the die-cutting and packaging line before mounting the core and the ring.

15    2.2.4 Preparation of the final plasters

The pressure-sensitive adhesive-coated cover film of 2.2.3 is introduced into an appropriate die-cutting line for plasters. 20    The release liner carrying, e.g., the cores, is introduced from a feed roll in such a manner that the cover film of the cores is contacted with the layer of adhesive of the cover film of 2.2.3 and they are bonded together by pressure (e.g., by using a pressure roll). The release liner of the cores is discarded. 25    Then the release liner with the rings is introduced from a second feed roll so that the rings are applied concentrically around the cores.

The release liner of the rings remains on the final product. 30    After lamination, the final plasters are die-cut, e.g., with a contoured die-cutter and then packaged.

### 2.3 Coating with masking films

The actual adhesive composition of the plaster, e.g., with incorporated active agents, is applied to a film, woven fabric

5 or non-woven fabric in the desired size minus the size of the surrounding ring of adhesive, which is subsequently applied, by a printing, coating or spraying process and optionally dried or allowed to solidify.

10 If coating is conducted by spreading, a mask is applied, e.g., on a siliconized film (release liner), by lamination before coating with the desired adhesive mixture.

### 15 Preparation of the perforated masking film

The perforated mask is prepared by applying a thin layer of a pressure-sensitive adhesive, which is also used for the subsequent ring of adhesive, on a paper film or polymer film

20 which is siliconized on both sides (intermediate liner 1). The coating thickness is approximately 1 to 20 g/m<sup>2</sup>. After coating, holes having the size and form which fulfill the requirements of the subsequent inner areas (plaster cores) of the final plasters are die-cut into the film in a suitable die-cutting or cutting

25 apparatus. The thickness of the film including the dried layer of adhesive must correspond exactly to the wet layer thickness of the desired plasters if the subsequent coating of the plaster cores is to be conducted by a solvent process otherwise the thickness must correspond to the dry layer thickness.

30

**Preparation of the plaster cores**

After coating, the siliconized side of the release liner is covered with the perforated masking film.

5 Then, the resultant laminate is further coated by filling the openings which had been left free in the perforated masking film with the material of the plaster cores. After drying of the fillings (if necessary), the laminate is wound up.

10

**Preparation of the plasters having cores and rings of adhesive**

15 In a suitable coating machine, the perforated masking film is removed from the release liner of the cores and the film (now carrying the cores on its silicone side) is coated again, namely in such a way that the material of the ring of adhesive fills the voids between the cores. The thickness of the coating is chosen according to the thickness of the cores taking the shrinking factor of the layer into consideration. After drying or hardening of the material of the ring the same thickness of the layer as that of the cores should result as far as possible.

20

25 After leaving the coater, the compound layer of adhesive is covered with a non-siliconized cover film.

30 The final plasters are now die-cut out of the laminate in a further die-cutting step. In this step, die-cutting tools are employed having a diameter which corresponds to the diameter of the plaster cores plus twice the breadth of the ring of adhesive.

#### 2.4 Preparation by covering with adhesive

In a further embodiment, the plaster cores are first prepared as described in 2.2.1. Subsequently, the release liner carrying the 5 cores is completely covered with an adhesive-coated cover film which is described in 2.2.3. Then, the final plasters are die-cut. In this step, die-cutting tools are used having a diameter with corresponds to the diameter of the plaster cores plus twice the breadth of the ring of adhesive.

10

## Claims

5 1. Flat self-adhering plaster having a multi-layer construction and reduced cold flow, characterized in that the layer of adhesive possesses a core of adhesive being a flowable adhesive and a ring of adhesive being an adhesive having reduced flowability which surrounds said core.

10 2. Plaster according to claim 1, characterized in that the core of adhesive contains a pharmaceutical or cosmetic active agent.

15 3. Plaster according to one of the preceding claims, characterized in that the multi-layer construction comprises a cover, a layer of adhesive having a core of adhesive as well as having a ring of adhesive, and removable carrier, which acts as a temporary cover and which is present on the side of the layer of adhesive opposite the cover.

20 4. Plaster according to claim 3, characterized in that the cover consists of a film of plastic, woven fabric or non-woven fabric.

25 5. Plaster according to claim 3 or 4, characterized in that the carrier consists of a film of plastic, paper or a laminate thereof.

30 6. Plaster according to claim 4 or 5, characterized in that the film of plastic is a film of polyethylene terephthalate, polyethylene, polypropylene or polyvinyl chloride.

7. Plaster according to claim 5, characterized in that the carrier possesses a release coating.

8. Plaster according to claim 7, characterized in that the release coating consists of a silicone layer or fluoro-silicone layer.

5

## Plaster having reduced cold flow

10

The present invention refers to a flat self-adhering plaster having a multi-layer construction and reduced cold flow, characterized in that the layer of adhesive possesses a core of adhesive being a flowable adhesive and a ring of adhesive being an adhesive having reduced flowability which surrounds said core.

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**DECLARATION FOR UTILITY OR  
DESIGN  
PATENT APPLICATION  
(37 CFR 1.63)**

Declaration Submitted OR  Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number	2727-110
First Named Inventor	Wilfried Fischer
<b>COMPLETE IF KNOWN</b>	
Application Number	/
Filing Date	
Group Art Unit	
Examiner Name	

As a below named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**"Patch With Reduced Cold Flow"**

the specification of which

(Title of the Invention)

is attached hereto  
OR

was filed on (MM/DD/YYYY)

as United States Application Number or PCT International

Application Number  and was amended on (MM/DD/YYYY)  (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Priority Claimed	Certified Copy Attached? YES	NO
DE299 11 111.3	Germany	06/25/1999	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.
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(July 1998)

Express Mail No. EK 839446714US

## DECLARATION — Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(e) of any PCT International application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56 which became available between the filing date of the prior application and the national or PCT International filing date of this application.

U.S. Parent Application or PCT Parent Number	Parent Filing Date (MM/DD/YYYY)	Parent Patent Number (If applicable)

Additional U.S. or PCT International application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith:  Customer Number  →  Place Customer Number Bar Code Label here  
OR  
 Registered practitioner(s) name/registration number listed below

Name	Registration Number	Name	Registration Number
Joseph C. Sullivan	18,720	Ronald E. Brown	32,200
Gerald Levy	24,419	John F. Gulbin	33,180
Ronald R. Santucci	28,988		

Additional registered practitioner(s) named on supplemental Registered Practitioner Information sheet PTO/SB/02C attached hereto.

Direct all correspondence to:  Customer Number or Bar Code Label  OR  Correspondence address below

Name	Ronald R. Santucci			
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City	New York	State	NY	ZIP
Country	U.S.A.	Telephone	212-687-6000	Fax
				212-682-3485

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name of Sole or First Inventor:  A petition has been filed for this unsigned inventor

Given Name (first and middle if any)		Family Name or Surname					
Wilfried		Fischer					
Inventor's Signature					Date		
Residence: City	Munich	State		Country	Germany	Citizenship	German
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Post Office Address							
City	Munich	State		ZIP	D-80807	Country	Germany

Additional inventors are being named on the        supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto

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## DECLARATION

### ADDITIONAL INVENTOR(S) Supplemental Sheet Page 3 of 3

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname					
Hubert		Kaffl						
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Post Office Address								
City	Munich	State		ZIP	D-80807	Country	Germany	
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor						
Given Name (first and middle [if any])			Family Name or Surname					
Petra		Huber						
Inventor's Signature							Date	
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Post Office Address								
City	Munich	State		ZIP	D-80807	Country	Germany	
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor						
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Clifton		Zimmermann						
Inventor's Signature							Date	
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